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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,549	08/03/2001	Jeffrey C. Rapp	AVI 013N	1388

26739 7590 01/17/2006

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EXAMINER	
MCGILLEM, LAURA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,549	RAPP, JEFFREY C.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-96,121-134 and 148-155* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-96,121,123-132,134 and 148-155* is/are rejected.

7)☐ Claim(s) *122 and 133* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *1/6/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *After Final amendment*.

DETAILED ACTION

It is noted that Applicant has submitted an After Final Amendment, filed 12/8/2005. The After Final amendment has been entered into the record and will be considered by the Examiner. Applicant has amended claims 129-134 in response to rejection under the second paragraph of 35 U.S.C. 112.

The finality of the Office action, mailed 7/27/2005 is withdrawn. Claims 88-96, 121-134 and 148-155 are pending.

The indicated allowability of claims 88-96, 121-134 and 148-155 is withdrawn in view of the newly discovered reference(s) to a DNA molecule that hybridizes to the nucleotide sequence of SEQ ID NO:67. Rejections based on the newly cited reference(s) follow.

Specification

The disclosure is objected to because of the following informalities:

On page 67, line 21 of the specification there is an open box (□) preceding the word "esterdiol". Appropriate correction is required.

Page 37, line 4 contains a blank where there should be a GenBank Accession No. for SEQ ID NO:67.

Page 26, line 6, contains an executable Internet address. It should be amended to remove "http://" so that it reads "--www.ncbi.nlm.nih.gov--".

The abstract of the disclosure is objected to because it contains more than 150 words. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Objections

Claims 129-134 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are drawn to an expression vector of claim 121 in various cell types. Regardless of the type of cell the expression vector is contained within, the expression vector has not changed. Placing the vector in a different cell type does not place further limitations on the expression vector.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 148-155 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 148 is vague and indefinite because it recites the phrase "operably linked to a heterologous peptide" after recitation of multiple nucleotide sequences and hybridization conditions, and it is not clear what is operably linked to a heterologous polypeptide.

Claim 148 is vague and indefinite because it is drawn to nucleotide sequences "operably linked to a heterologous polypeptide" and it is not clear how a nucleotide sequence can be operably linked to a heterologous peptide. It would be remedial for the claims to recite, " operably linked to a nucleotide sequence encoding a heterologous polynucleotide".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 88-96, 121-134 and 148-155 are all drawn to DNA molecules comprising a nucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO:67 in the presence of 1.0 M Na ion at a temperature of 60°C. The specification discloses said condition as "stringent" for long probes, as compared to "moderate stringency" or "high stringency" (see paragraph 0060). At the claimed hybridization conditions and absent evidence to the contrary, the skilled artisan would reasonably expect nucleotide

sequences which are 87-100% identical to the claimed SEQ ID NO:67 to be able to hybridize to SEQ ID NO:67.

Claims 88-89, 95-96, 121, 123, 131, 134, 148-149 and 154-155 rejected under 35 U.S.C. 102(b) as being anticipated by Phi-Van et al (of record). Phi-Van et al teach a nucleotide sequence (GenBank Accession No. X98408) from the chicken lysozyme gene transcription enhancer region that is 96% identical to nucleotides 1-237, 261-1564 of SEQ ID NO:67. Phi-Van et al teach that a chicken lysozyme gene promoter comprising a 5' matrix attachment region was operably linked to a chloramphenicol acetyltransferase (CAT) reporter gene in a plasmid including a SV40 polyadenylation sequence (see page 10736, left column, last paragraph, and right column, Figure 1, in particular), which reads on an isolated DNA molecule and an expression vector, comprising a gene expression controlling region or 5' matrix attachment region comprising a nucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO:67. Phi-Van teach that the expression plasmids were transfected into cultured NIH 3T3 fibroblasts for CAT expression assays (see page 10736, right column, last paragraph, for example), which reads on an isolated cultured cell comprising a gene expression controlling region comprising a nucleotide sequence that hybridizes to the nucleotide sequence of SEQ ID NO:67 operably linked to a heterologous polypeptide.

Claims 88-89, 121 and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by von Kries et al (Nucleic Acids Res. 1990. Vol. 18(13), pp. 3881-5). von Kries et al teach a nucleotide sequence (GenBank Accession No. X52989) from the chicken lysozyme gene 5' matrix attachment region that is 98% identical to nucleotides

2011-2671 of SEQ ID NO:67 and strongly curved. von Kries et al teach that an isolated DNA sequence was cloned into a plasmid vector for sequencing (see page 3881, right column, 1st paragraph and page 3882, left column, 2nd paragraph, for example), which reads on an isolated DNA molecule and an expression vector comprising a nucleotide sequence or an intrinsically curved region of DNA that hybridizes to the nucleotide sequence of SEQ ID NO:67.

Claims 88, 90, 121, 124, 129-131 and 148-151 are rejected under 35 U.S.C. 102(b) as being anticipated by Grewal et al (Mol Cell Biol. 1992, Vol.12 (5) pp.2339-50). Grewal et al teach a nucleotide sequence from the chicken lysozyme gene enhancer region that is located 6.1 kb upstream of the lysozyme transcription initiation site and which is 100% identical to nucleotides 5848-5934 of SEQ ID NO:67 (see page 2344, Figure 4 in particular). The -6.1kb enhancer element was isolated and cloned into a reporter plasmid (see page 2340, left column), which reads on an isolated DNA molecule and an expression vector comprising a gene expression controlling region or a transcription enhancer comprising a nucleotide sequence that hybridizes to the sequence of SEQ ID NO:67. Grewal et al teach that the expression vector was transfected into chicken embryo fibroblasts and chicken DU249 cells (see page 2340, right column, last paragraph), which reads on an isolated cell comprising a gene expression controlling region or transcription enhancer comprising a nucleotide sequence that hybridizes to the sequence of SEQ ID NO:67 linked to a heterologous polypeptide in a cultured avian or chicken cell.

Claims 88, 94, 121, 128-132 and 148-152 are rejected under 35 U.S.C. 102(b) as being anticipated by Renkawitz et al (Cell, 1984. Vol. 37(2), p. 503-10). Renkawitz et al teach a nucleotide sequence (GenBank Accession No. M12532) from the chicken lysozyme gene promoter region that is 100% identical to nucleotides 11563-11877 of SEQ ID NO:67, which has been cloned into a recombinant plasmid and injected into chicken oviduct cells (see page 504, left column, Figure 1 and page 509, left column, 2nd and 3rd paragraph), which reads on an isolated DNA molecule or an expression vector comprising a gene expression controlling region or a proximal lysozyme promoter comprising a nucleotide sequence that hybridizes to the sequence of SEQ ID NO:67 and a cultured avian chicken cell comprising a nucleotide sequence that hybridizes to the sequence of SEQ ID NO:67. Renkawitz et al teach that the promoter is linked to a gene for T antigen (see page 504, left column, 2nd paragraph, bridging to right column, 1st paragraph) which reads on an isolated cell comprising a gene expression controlling region that hybridizes to the nucleotide sequence of SEQ ID NO:67 operably linked to a heterologous polypeptide.

Claims 88, 90-91, 121, 124-125, 129-131 and 148-151 are rejected under 35 U.S.C. 102(b) as being anticipated by Steiner et al (of record). Steiner et al teach a nucleotide sequence (E-0.2kb) (GenBank Accession No. X05461) from the chicken lysozyme gene transcription enhancer region that is 98% identical to nucleotides 9160-9329 of SEQ ID NO:67 (see page 4174, Figure 8). Steiner et al also teach a nucleotide sequence (GenBank Accession No. X05463) from the chicken lysozyme gene transcription enhancer region that is 98% identical to nucleotides 9325-9626 of SEQ ID

NO:67 and a negative regulatory element (see page 4174, Figure 8). Steiner et al teach that the transcription enhancer region and negative regulatory element were isolated and cloned into plasmids containing the CAT gene (see page 4164, for example), which reads on an isolated DNA molecule comprising a gene expression controlling region or transcription enhancer or negative regulatory element, and reads on an expression vector comprising a gene expression controlling region or transcription enhancer or negative regulatory element comprising a nucleotide sequence that hybridizes to SEQ ID NO:67. Steiner et al teach that the plasmids were transfected into chicken embryo fibroblast cells (CEF38) for CAT expression assays (see page 4166, last paragraph; page 4166, 2nd and 3rd paragraph, for example) which reads on an isolated cultured avian or chicken cell comprising a gene expression controlling region comprising a nucleotide sequence that hybridizes to SEQ ID NO:67 operably linked to a heterologous polypeptide.

Claims 88, 92, 121, 126, 148-149 are rejected under 35 U.S.C. 102(b) as being anticipated by Hecht et al (of record). Hecht et al teach a nucleotide sequence (GenBank Accession No. X12509) from the chicken lysozyme gene transcription enhancer region that is 99% identical to nucleotides 9621-9666, 9680-10060 of SEQ ID NO:67 (see page 2070, Figure 6). Hecht et al teaches a DNA sequence which stimulates transcription in a hormone dependent manner which has been operably linked to a CAT gene in a vector for transfection into a hormone receptor containing cell line (see page 2063, right column, 2nd and 3rd paragraph, for example), which reads on an isolated DNA molecule and an expression vector comprising a gene expression

controlling region comprising at least one hormone responsive element and comprising a nucleotide sequence that hybridizes to SEQ ID NO:67. The expression vector was transfected into a human ductal carcinoma line T-47D, (see page 2071, right column, last paragraph, for example), which reads on an isolated cultured cell comprising a nucleotide sequence that hybridizes to the sequence of SEQ ID NO:67.

Claims 88, 93, 121 and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by Stumph et al (PNAS, 1984. Vol. 81(21). Pp. 6667-71). Stumph et al teach a nucleotide sequence (GenBank Accession No. K02907) that is a CR1 chicken enhancer repeat element that is 87% identical to nucleotides 10926-11193 of SEQ ID NO:67(see page 6669, Figure 2, for example). Stumph et al teach that CR1 sequences were cloned for sequencing into a plasmid vector (see page 6667, right column, 2nd and 3rd paragraph, for example), which reads on an isolated DNA molecule or an expression vector comprising a gene expression controlling region or an avian CR1 repeat element that hybridizes to the nucleotide sequence of SEQ ID NO:67.

Conclusion

No claims are allowed. Claims 122 and 133 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
1/11/2006